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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,088	07/25/2003	James F. Young	10271-072-999	5542

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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,088	YOUNG ET AL.	
	Examiner	Art Unit	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 7/25/03.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-84 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-84 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-29, drawn to a method of treating a viral infection using RSV antigens, are classified in class 424, subclass 211.1.

II. Claims 30-33, drawn to a method of treating a viral infection using humanized antibodies, are classified in class 424, subclass 211.1.

III. Claims 34-49, drawn to a pharmaceutical composition, are classified in class 424, subclass 211.1.

IV. Claims 50-71, drawn to a method of treating a viral infection using PIV antigens, are classified in class 424, subclass 211.1.

V. Claims 72-84, drawn to a method of treating a viral infection using RSV and PIV antigens, are classified in class 424, subclass 211.1.

The inventions are independent or distinct, each from the other because:

Inventions I, II and IV are unrelated because they are methods with different modes of operation, with respect to starting materials, physiological mechanisms, protocol procedures, and end products. Briefly, group I is drawn to a treatment method using RSV antigens. In contrast, group II is drawn to using humanized antibodies and group III is drawn to using PIV antigens for treatment of viral infections. All groups have separate starting materials and thus, the viral infection drawn to each invention are treated via different mechanisms; therefore, each method is patentably distinct.

Inventions II and V are unrelated because they are methods with different modes of operation, with respect to starting materials, physiological mechanisms, protocol procedures, and end products. Briefly, group II is drawn to using humanized antibodies for treatment of viral infections. In contrast, group V is drawn to a method of treating a viral infection using RSV and PIV antigens. All groups have separate starting materials and thus, the viral infection drawn to each invention are treated via different mechanisms; therefore, each method is patentably distinct.

Inventions I and IV are related to V as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). As evidenced by the claims, invention I requires the use of RSV antigens but not of PIV antigens. Invention IV requires the use of PIV antigens but not of RSV antigens. Both inventions I and IV has utility by themselves and the combination does not require the particulars of the subcombination for patentability.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the pharmaceutical composition as claimed in group I may be used in a materially different process, such as, for protein purification. Thus, the inventions are patentably distinct.

Inventions II, IV and V are unrelated to III. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of II, IV and V require the use of a different pharmaceutical composition from that of group III; thus, II, IV and V use compositions of different designs. Additionally, the specification does not disclose a combined use of the inventions. Thus, these inventions are patentably distinct.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

A further election of species is required following the election of group I or III.

This application contains claims directed to the following patentably distinct species:

A. The RSV antigen is elected from:

1. SEQ ID NO:390;
2. SEQ ID NO:391;
3. SEQ ID NO:392;
4. SEQ ID NO:393;
5. SEQ ID NO:394;

6. SEQ ID NO:395;

7. SEQ ID NO:396;

8. SEQ ID NO:397;

9. SEQ ID NO:398;

10. Group A RSV;

11. Group B RSV;

12. RSV F protein;

13. nucleoprotein;

14. phosphoprotein;

15. matrix protein;

16. small hydrophobic protein;

17. RNA-dependent RNA polymerase; and

18. RSV G protein.

The species are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for treatment of viral infections, the different sequences have different effects. Furthermore, the specification does not disclose that they are capable of use together.

A further election of species is required following the election of group I, III or IV.

B. The APV antigen is elected from:

19. nucleoprotein;

20. phosphoprotein;

21. matrix protein;

22. small hydrophobic protein;

23. RNA-dependent RNA polymerase;

24. APV G protein;

25. APV F protein;

26. SEQ ID NO:424;

27. SEQ ID NO:425;

28. SEQ ID NO:426;

29. SEQ ID NO:427;

30. SEQ ID NO:428; and

31. SEQ ID NO:429.

The species are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for treatment of viral infections, the different sequences have different effects. Furthermore, the specification does not disclose that they are capable of use together.

A further election of species is required following the election of group I, III or IV.

C. The hMPV antigen is elected from:

32. SEQ ID NO:399;

23. SEQ ID NO:400;

34. SEQ ID NO:401;

35. SEQ ID NO:402;

36. SEQ ID NO:403;

37. SEQ ID NO:404;

38. SEQ ID NO:405;

39. SEQ ID NO:406;

40. SEQ ID NO:420;

41. SEQ ID NO:421;

42. nucleoprotein;

43. phosphoprotein;

44. matrix protein;

45. small hydrophobic protein;

46. RNA-dependent RNA polymerase;

47. hMPV G protein; and

48. hMPV F protein.

The species are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different

inventions represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for treatment of viral infections, the different sequences have different effects. Furthermore, the specification does not disclose that they are capable of use together.

A further election of species is required following the election of group I or III.

D. The first antibody is elected from:

49. **one** of those listed in claim 22.

The species are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for treatment of viral infections, the different sequences have different effects. Furthermore, the specification does not disclose that they are capable of use together.

A further election of species is required following the election of group I or IV.

E. The viral infection is

50. RSV and hMPV; and

51. RSV and APV.

The species are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of

operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for the different types of viral infections, the different sequences have different effects. Furthermore, the specification does not disclose that they are capable of use together.

A further election of species is required following the election of group IV or V.

F. The PIV antigen is elected from:

52. **one** amino acid sequence from SEQ ID NO:407-419;

53. nucleocapsid phosphoprotein ;

54. L protein;

55. matrix protein;

56. HN glycoprotein;

57. RNA-dependent RNA polymerase;

58. Y1 protein;

59. D protein;

60. C protein;

61. PIV F protein;

62. PIV G protein;

63. nucleoprotein; and

64. small hydrophobic protein.

The species are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for treatment of viral infections, the different sequences have different effects. Furthermore, the specification does not disclose that they are capable of use together.

A further election of species is required following the election of group IV.

G. The antibody that immunospecifically binds to:

65. human PIV type 1;

66. human PIV type 2;

67. human PIV type 3; and

68. human PIV type 4.

The species are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for treatment of viral infections, the different sequences have different effects. Furthermore, the specification does not disclose that they are capable of use together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims are generic because the claims are not limited to a specific treatment, viral infection or composition.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Joint Inventors

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusions

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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